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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/552,206   | 09/14/2006  | Irina Velikyan       | PH0333              | 6320             |
| 36335 7590 02/12/2009<br>GE HEALTHCARE, INC.<br>IP DEPARTMENT<br>101 CARNEGIE CENTER<br>PRINCETON, NJ 08540-6231 |             |                      |                     |                  |
| EXAMINER<br>PERREIRA, MELISSA JEAN   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1618   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/552,206

**Applicant(s)**

VELIKYAN ET AL.

**Examiner**

MELISSA PERREIRA

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-19 are pending in the application. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

### ***Response to Arguments***

1. Applicant's arguments filed 2/3/09 have been fully considered but they are not persuasive.
2. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (WO03/059397A2) in view of Bottcher et al. (US 5,439,863) and further in view of Maier-Borst et al. (GB 2056471A) as stated in the office action mailed 11/3/08.
3. Applicant asserts that Bottcher et al. does not discuss how microwave technology could be used as an input of energy and does not deem these inputs of energy as important parts of its patent.
4. Bottcher et al. discloses the preparation of metal complexes (metal-multitoothed chelating ligand complex) via microwave irradiation which allows for a continuous conversion, single-stage reaction with short reaction time and ease of separation of the formed complexes (Bottcher et al. column 4, line 19; column 5, lines 66+; column 6, lines 1-5). Griffiths et al. teaches of the preparation of a metal-NOTA/DOTA ligand complex (i.e. <sup>68</sup>Ga-radiolabelled complex) and since the microwave technique was known in the art (Bottcher et al.) for the preparation of such metal-multitoothed chelating ligand complexes one would have a reasonable expectation of success for preparing

the metal-ligand complex, <sup>68</sup>Ga-radiolabelled complex, of Griffiths et al. via with the faster and more efficient microwave technique of Bottcher et al.

5. Also, the reference of Bottcher et al. is a patent and therefore contains an enabling disclosure for microwave technology, thus, it is applicant's burden to provide some reasoning and/or evidence that the Bottcher reference is not enabling for microwave energy technology. The limitation of using microwave technology to form the complexes does not need to be exemplified and the assertion that Bottcher et al. does not deem microwave as an important part of its patent is merely the opinion of the applicant.

6. Applicant asserts that Bottcher et al. does not teach microwaves are preferred over using ultrasound or laser beams as inputs of energy.

7. The limitation of using microwaves to form the complexes does not need to be exemplified. Bottcher et al. discloses the preparation of metal complexes (metal-multitoothed chelating ligand complex) via microwave irradiation which allows for a continuous conversion, single-stage reaction with short reaction time and ease of separation of the formed complexes (Bottcher et al. column 4, line 19; column 5, lines 66+; column 6, lines 1-5). Bottcher et al. explicitly states microwave as an energy input and thus it is obvious to one skilled in the art that microwave is a viable energy input. Griffiths et al. teaches of the preparation of a metal-NOTA/DOTA ligand complex (i.e. <sup>68</sup>Ga-radiolabelled complex) and since the microwave technique was known in the art (Bottcher et al.) for the preparation of such metal-multitoothed chelating ligand complexes one would have a reasonable expectation of success for preparing the

metal-ligand complex, <sup>68</sup>Ga-radiolabelled complex, of Griffiths et al. via with the faster and more efficient microwave technique of Bottcher et al.

8. Applicant asserts that Bottcher et al. does not disclose, teach or suggests using a microwave oven as disclosed in the present invention to enhance or improve efficiency and reproducibility of the neutral metal complex salt formation.

9. Bottcher et al. explicitly states microwave as an energy input and thus it is obvious to one skilled in the art that microwave is a viable energy input. Bottcher et al. teach that microwave allows for a continuous conversion, single-stage reaction with short reaction time and ease of separation of the formed complexes (Bottcher et al. column 4, line 19; column 5, lines 66+; column 6, lines 1-5). The instant claims recite "microwave activation" and do not provide any active steps over standard microwave activation, therefore the microwave activation of Bottcher et al. encompasses that of the instant claims and is capable of the same functions, such as to enhance or improve efficiency and reproducibility and has the same properties.

10. Applicant asserts that Bottcher et al. teaches away from the present invention where "A reference may be said to teach away when a person of ordinary skill, upon [examining] the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." Para-Ordnance Mfg. v. SGS Importers Int'l, 73 F.3d 1085 (Fed. Cir. 1995)

11. The Para-Ordnance Mfg. v. SGS Importers Int'l, 73 F.3d 1085 (Fed. Cir. 1995)/ Para-Ordnance Manufacturing Inc. v. SGS Importers International Inc., 37 USPQ2d 1237 (Fed. Cir. 1995) states that the Browning Hi-Power reference used "teaches away

from using convergence at all" because it supports the magazine "with a rounded frame that does not converge". The Browning Hi-Power reference explicitly teaches away from convergence by stating, "does not converge" which does not apply to the reference of Bottcher et al. Bottcher et al. explicitly states microwave as an energy input to form the complexes of the disclosure and thus it is obvious to one skilled in the art that microwave is a viable energy input to form the complexes of the disclosure and does not teach away.

12. Applicant asserts that Bottcher et al. does not use the microwave activation technique disclosed in the present invention to carry out the coordination chemistry.

13. The limitation of using microwaves to form the complexes does not need to be exemplified. Bottcher et al. discloses the preparation of metal complexes (metal-multitoothed chelating ligand complex) via microwave irradiation which allows for a continuous conversion, single-stage reaction with short reaction time and ease of separation of the formed complexes (Bottcher et al. column 4, line 19; column 5, lines 66+; column 6, lines 1-5). Bottcher et al. explicitly states microwave as an energy input and thus it is obvious to one skilled in the art that microwave is a viable energy input. Griffiths et al. teaches of the preparation of a metal-NOTA/DOTA ligand complex (i.e. <sup>68</sup>Ga-radiolabelled complex) and since the microwave technique was known in the art (Bottcher et al.) for the preparation of such metal-multitoothed chelating ligand complexes one would have a reasonable expectation of success for preparing the metal-ligand complex, <sup>68</sup>Ga-radiolabelled complex, of Griffiths et al. via with the faster and more efficient microwave technique of Bottcher et al.

14. Applicant asserts that the objective of Maier-Borst et al. was to synthesize an anion exchange resin for the separation of gallium-68 from germanium-68 thus avoiding the use of EDTA for elution as it was done before the 1980's. Unlike Maier-Borst et al., in the present invention, gallium-68 is eluted from a commercial generator already in ionic form.

15. The instant claims are drawn to the method of obtaining  $^{68}\text{Ga}$  from a  $^{68}\text{Ge}/^{68}\text{Ga}$  generator with an anion exchanger, such as polystyrene-divinylbenzene and a dilute HCl solution. The reference of Maier-Borst et al. is drawn to process for preparing an ion (anion)-exchanger and further is drawn to the method of obtaining  $^{68}\text{Ga}$  from a  $^{68}\text{Ge}/^{68}\text{Ga}$  generator with the ion (anion)-exchanger, such as styrene and divinylbenzene and a dilute HCl solution (Maier-Borst et al. p1, lines 59-63). The ion (anion)-exchanger of Maier-Borst et al. encompasses the ion (anion)-exchanger of the instant claims and is capable of the same functions (i.e. labeling efficiency, etc.) and has the same properties. Also, the instant claims do not provide the limitations of a preconcentration procedure which is asserted as necessary by the applicant.

### ***Double Patenting***

16. Claims 8-12 and 14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1,3-7,11,13,15 of copending Application No. 10/552,134.

17. Applicant asserts that the claims of copending application 10/552,134 will be amended or cancelled if the instant application is indicated to be allowable.

18. Claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/552,134.
19. Claims 1,2,6-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/358,681.
20. Applicant asserts that a terminal disclaimer will be filed for applications 11/358,681 and 10/552,134 once the instant application is indicated as allowable.

### ***Conclusion***

21. No claims are allowed at this time.
22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/  
Examiner, Art Unit 1618